The Office Action has held that Pittenger et al., patent discloses a method of administering stem cell products such as mesenchymal stem cells (MSCs) directly to a heart or directly to the damaged portion of the myocardium. The Pittenger et al., patent also discloses that MSC therapy can be provided by several routes of administration including intravenously, intracoronarily, or directly to the heart. The Office Action concludes that the Pittenger et al., patent discloses a method having an identical active step and identical structural elements while achieving identical effects as recited in the presently pending independent claims.

When read more specifically, the Pittenger et al., patent discloses that stem cells themselves must be cultured *in vitro* prior to transplantation into the body. It was previously unknown that stem cell products, such as those recited in the presently pending claims, could be used in treating heart failure. The presently pending claims recite use of stem cell products that are transplanted directly into the body of a patient without need of *in vitro* differentiation or alteration. It was previously thought that the stem cells must be differentiated or genetically altered prior to insertion into the body in order for the stem cells to achieve the desired function. The presently claimed invention instead recites that the products from the stem cells can be placed directly into a location for treating heart failure and that the stem cell products alone are sufficient for treating heart failure. The cited prior art reference discloses the use of altered or differentiated stem cells for treating heart failure. The Office Action has held that the stem cells disclosed in the prior art are identical to the stem cell products recited in the pending claims; however, there is absolutely no disclosure that connects the stem cells disclosed in the prior art and stem cell products as recited in the presently pending independent claims. The stem cell products recited in the presently pending claims are secretions from stem cells found in stem cells containing supernatant, not merely stem cells as recited in the prior art.

There is no disclosure in the Pittenger et al., patent that the use of products formed by stem cells alone, without the presence of the stem cells, could be used in

treating heart failure, improving cardiac function, enriching or regenerating damaged myocardium. All that is disclosed by the Pittenger et al., patent is that stem cells can be administered to improve function after a myocardial infarction. Absent a teaching in the Pittenger et al., patent for the use of stem cell products for treating myocardial infarction, the claims are patentable over the Pittenger et al., patent and reconsideration of the rejection is respectfully requested.

Claims 1, 2, 6, and 7 stand rejected under 35 U.S.C. §102(b) as being anticipated by the Tomita et al., reference. Reconsideration of the rejection under 35 U.S.C. §102(b), as anticipated by the Tomita et al., reference, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action has held that the Tomita et al., reference discloses a method of treating heart failure, improving cardiac function, enriching or regenerating damaged myocardium by administering stem cell products, such as MSCs, directly to the heart or damaged myocardium. Further, the Tomita et al., reference discloses that transplantation of MSCs improved infarcted heart function, which is identical to the methods recited in the presently pending independent claims.

When read more specifically, the Tomita et al., reference discloses that stem cells themselves must be cultured *in vitro* prior to transplantation into the body. It was previously unknown that stem cell products, such as those recited in the presently pending claims, could be used in treating heart failure. The presently pending claims recite use of stem cell products that are transplanted directly into the body of a patient without need of *in vitro* differentiation or alteration. It was previously thought that the stem cells must be differentiated or genetically altered prior to insertion into the body in order for the stem cells to achieve the desired function. The presently claimed invention instead recites that the products from the stem cells can be placed directly into a location for treating heart failure and that the

stem cell products alone are sufficient for treating heart failure. The cited prior art reference discloses the use of altered or differentiated stem cells for treating heart failure. The Office Action has held that the stem cells disclosed in the prior art are identical to the stem cell products recited in the pending claims; however, there is absolutely no disclosure that connects the stem cells disclosed in the prior art and stem cell products as recited in the presently pending independent claims. The stem cell products recited in the presently pending claims are secretions from stem cells found in stem cells containing supernatant, not merely stem cells as recited in the prior art.

There is no disclosure in the Tomita et al., reference that the use of products formed by stem cells alone, without the presence of the stem cells, could be used in treating heart failure, improving cardiac function, enriching or regenerating damaged myocardium. All that is disclosed by the Tomita et al., reference is that stem cells can be administered to improve function after a myocardial infarction. Absent a teaching in the Tomita et al., reference for the use of stem cell products for treating myocardial infarction, the claims are patentable over the Tomita et al., reference and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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Dated: May 17, 2006

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Marie M. Lally